



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-0278]

#### Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry; Reopening of the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance entitled “Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry,” which was announced in the *Federal Register* of January 25, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening the comment period on the draft guidance published January 25, 2023 (88 FR 4797). Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be

posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2022-D-0278 for "Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including

the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Eileen Abt, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1700; or Philip Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of January 25, 2023 (88 FR 4797), we published a notice of availability for a draft guidance entitled “Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry.” This action opened a docket with a 60-day comment period to receive comments related to action levels for lead in processed food intended for babies and young children.

We have received a request for a 60-day extension of the comment period for the draft guidance to provide additional time to provide analytical data. In the interest of balancing the public health importance of establishing action levels for lead in food labeled for babies and young and granting additional time to submit comments before we finalize the draft guidance, we have concluded that it is reasonable to reopen the comment period for 30 days, until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 30 days allows adequate time for interested persons to submit comments.

Dated: April 3, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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